

decimeter in length. Calculate the specific rotation on an anhydrous basis.

(8) *Identity*. Using a 0.002 percent solution of the sample in 0.1M sodium bicarbonate solution and a suitable ultraviolet spectrophotometer, record the ultraviolet spectrum from 220 to 340 nanometers. The spectrum compares qualitatively to that of the cefazolin working standard similarly tested.

[39 FR 19040, May 30, 1974, as amended at 42 FR 18059, Apr. 5, 1977; 50 FR 19919, May 13, 1985]

§ 442.12 Cefoperazone sodium.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Cefoperazone sodium is the sodium salt of (6*R*, 7*R*)-7-[(*R*)-2-(4-ethyl-2,3-dioxo-1-piperazinecarboxamido)-2-(*p*-hydroxyphenyl)acetamido]-3-[[1-methyl-1*H*-tetrazol-5-yl]thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate. It is a white to off-white crystalline powder or a lyophilized powder. It is so purified and dried that:

(i) Its cefoperazone content is not less than 870 micrograms and not more than 1,015 micrograms of cefoperazone per milligram on an anhydrous basis.

(ii) Its moisture content is not more than 5.0 percent, except if it is the lyophilized powder, its moisture content is not more than 2.0 percent.

(iii) The pH of an aqueous solution containing 250 milligrams per milliliter is not less than 4.5 and not more than 6.5.

(iv) It passes the identity test if the retention times of the sample and working standard agree within ± 3.0 percent.

(v) It is crystalline, except if it is the lyophilized powder.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples*. In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for cefoperazone content, moisture, pH, identity, and crystallinity (if it is not the lyophilized powder).

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay—(1) Cefoperazone content*. Proceed as directed in § 436.338 of this chapter.

(2) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(3) *pH*. Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 250 milligrams per milliliter.

(4) *Identity*. From the high-performance liquid chromatograms of the sample and the cefoperazone working standard determined as directed in paragraph (b)(1) of this section, calculate the adjusted retention times of the cefoperazone in the sample and standard solutions as follows:

Adjusted retention time of cefoperazone = $t - t_a$

where:

t = Retention time measured from point of injection into the chromatograph until the maximum of the cefoperazone sample or working standard peak appears on the chromatogram; and

t_a = Retention time measured from point of injection into the chromatograph until the maximum of nonretarded solute appears in the chromatogram.

The sample and the cefoperazone working standard should have corresponding adjusted cefoperazone retention times within ± 3.0 percent.

(5) *Crystallinity*. Proceed as directed in § 436.203(a) of this chapter.

[51 FR 36688, Oct. 15, 1986, as amended at 55 FR 11583, Mar. 29, 1990]

§ 442.12a Sterile cefoperazone sodium.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Sterile cefoperazone sodium is the sodium salt of (6*R*, 7*R*)-7-[(*R*)-2-(4-ethyl-2,3-dioxo-1-piperazinecarboxamido)-2-(*p*-hydroxyphenyl)acetamido]-3-[[1-methyl-1*H*-tetrazol-5-yl]thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate. It is a white to off-white crystalline powder or it may be a lyophilized powder. It is so purified and dried that:

(i) If the cefoperazone sodium is not packaged for dispensing, its cefoperazone content is not less than 870 micrograms and not more than 1,015 micrograms of cefoperazone per milligram on an anhydrous basis. If the cefoperazone sodium is packaged for